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IMPACT OF THE NEW ADMINISTRATION ON FDA/LIFE SCIENCES COMPANIES

April 3, 2025

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George works with life sciences companies of all sizes to assist them in developing and marketing innovative products that are regulated by the US Food and Drug Administration, including drugs and biologics, medical devices, drug-device combination products, CBD and botanical products, medical foods and dietary supplements.

George has deep experience providing regulatory advice to pharmaceutical and biotech companies on lifecycle management issues, including regulatory exclusivities and FDA-facing patent issues. He is a leading expert on orphan drug matters, including orphan designation and exclusivity, and has successfully advocated on behalf of clients to FDA on matters related to prevalence, orphan subsets, and clinical superiority. George also regularly advises pharmaceutical and biotechnology companies on pediatric study and pediatric exclusivity issues arising under the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act.

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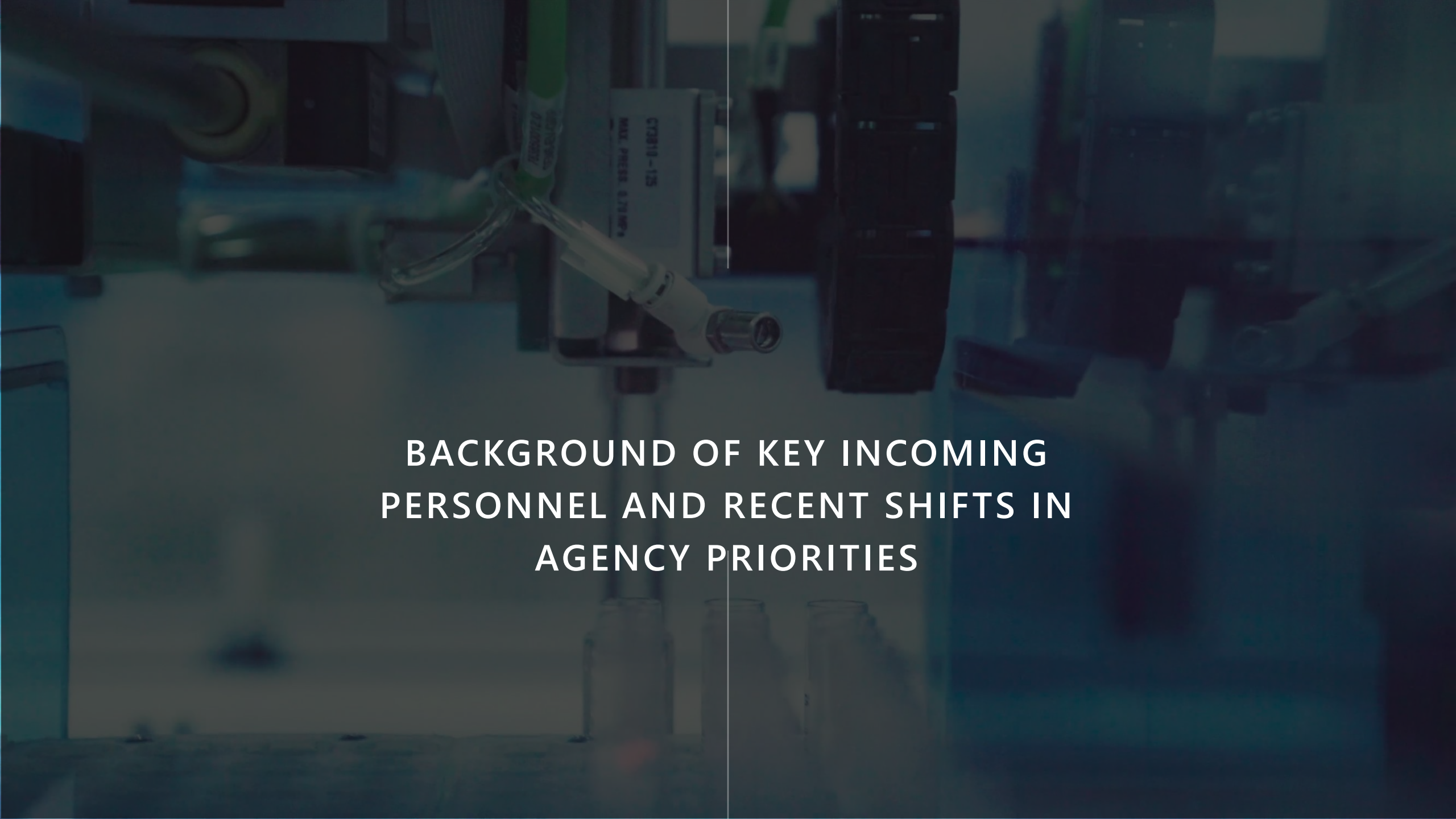
Arun G. Rao, who has held a series of distinguished government positions, helps clients navigate cutting-edge government investigations and criminal and civil enforcement actions, including fraud and consumer protection matters involving the DOJ, Federal Trade Commission, US Food and Drug Administration, US Consumer Product Safety Commission, US Department of Transportation, and other agencies, as well as high-stakes white collar work. He most recently served as a Deputy Assistant Attorney General in the US Department of Justice, where he oversaw the agency's Consumer Protection Branch.

Arun previously served in the White House Counsel's Office and as an Assistant US Attorney and Chief of the Southern Division of the US Attorney's Office for the District of Maryland, where he both supervised and directly handled federal criminal cases involving public corruption, fraud and financial crimes, immigration violations, and national security. He also previously served as the President of Investigative Group International (IGI), where he directed many sensitive and complex investigations and provided crisis management services. He brings more than 20 years of experience litigating and investigating complex criminal and civil matters involving the world's leading financial services, technology, pharmaceutical, healthcare, and consumer products companies, as well as universities and elected officials and candidates for office

AGENDA

1. Background of key incoming personnel at FDA and shifting priorities across all FDA programs, including food, drugs and biologics, medical devices, and cosmetics, as well as at the U.S Department of Justice;
2. Potential impact of staffing losses on enforcement and product reviews;
3. The Trump Executive Orders regarding deregulation;
4. Drug pricing and the Inflation Reduction Act;
5. Potential impact of tariffs on drug and biotech development; and
6. Likely areas where regulated industry can expect greater continuity.

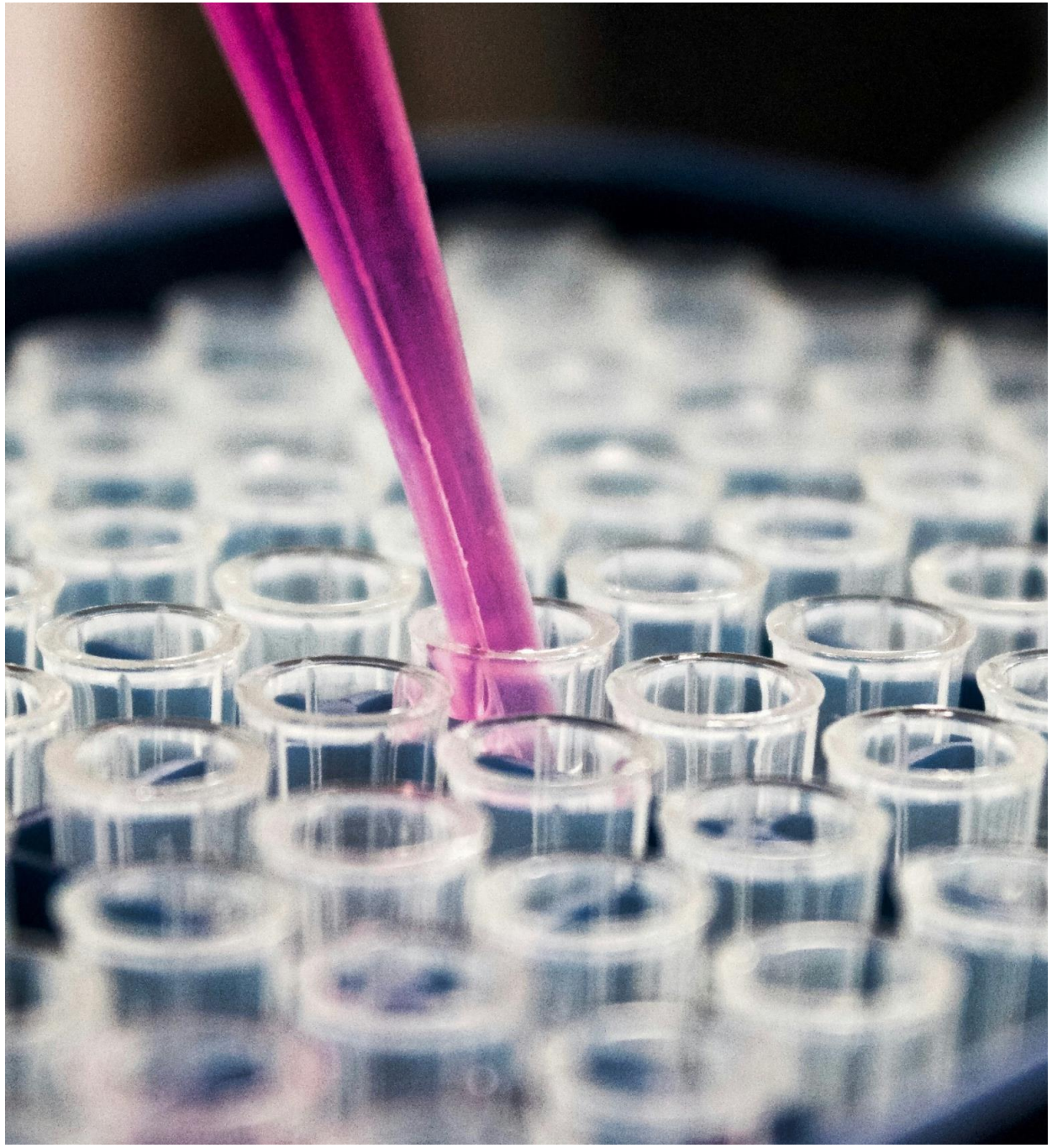


BACKGROUND OF KEY INCOMING PERSONNEL AND RECENT SHIFTS IN AGENCY PRIORITIES

AN UNPRECEDENTED MOMENT

- Major shifts in:
  - Agency leadership,
  - Regulatory priorities,
  - Enforcement efforts, and
  - Internal resources

  will impact program management and efficiency.



HHS SECRETARY ROBERT F. KENNEDY JR.

← **Post**

Robert F. Kennedy Jr ✓
@RobertKennedyJr

FDA's war on public health is about to end. This includes its aggressive suppression of psychedelics, peptides, stem cells, raw milk, hyperbaric therapies, chelating compounds, ivermectin, hydroxychloroquine, vitamins, clean foods, sunshine, exercise, nutraceuticals and anything else that advances human health and can't be patented by Pharma. If you work for the FDA and are part of this corrupt system, I have two messages for you: 1. Preserve your records, and 2. Pack your bags.

5:25 PM · Oct 25, 2024 · **6.5M** Views

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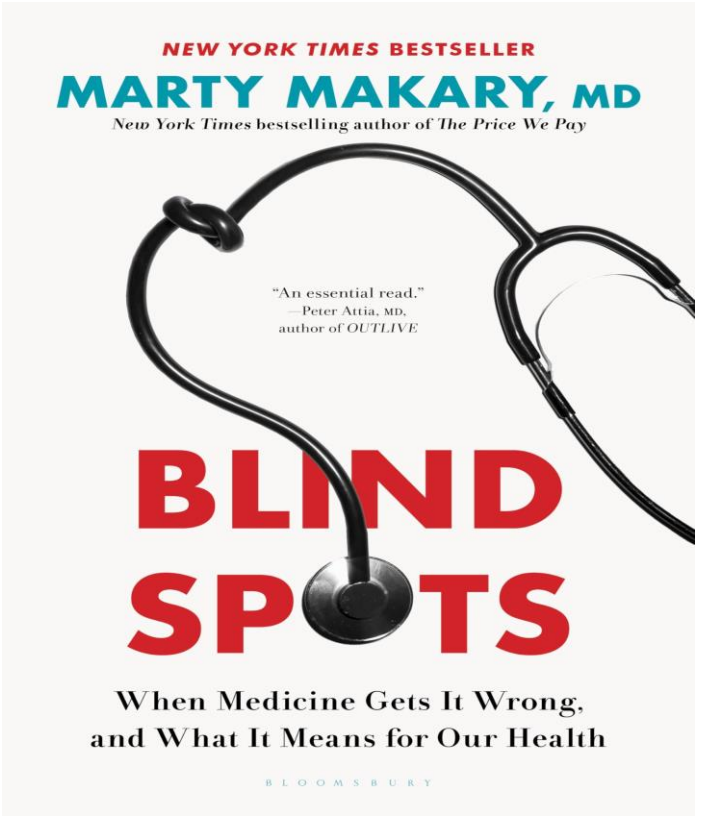
Post your reply Reply

SECRETARY ROBERT F. KENNEDY JR.'S PAST STATEMENTS AND ACTIONS

Suggest that Secretary Kennedy may seek to:

- permit manufacture and distribution of medical products that have not gone through FDA approval or clearance processes;
- permit marketing claims, including for some products that do not comply with all FDA regulations, that could disadvantage food, drug, and medical device that are compliant with FDA requirements; and/or
- prohibit manufacturing of food dyes and additives previously approved by FDA.

FDA COMMISSIONER DR. MARTIN MAKARY



COMMISSIONER MAKARY'S PAST WRITINGS AND PUBLIC STATEMENTS

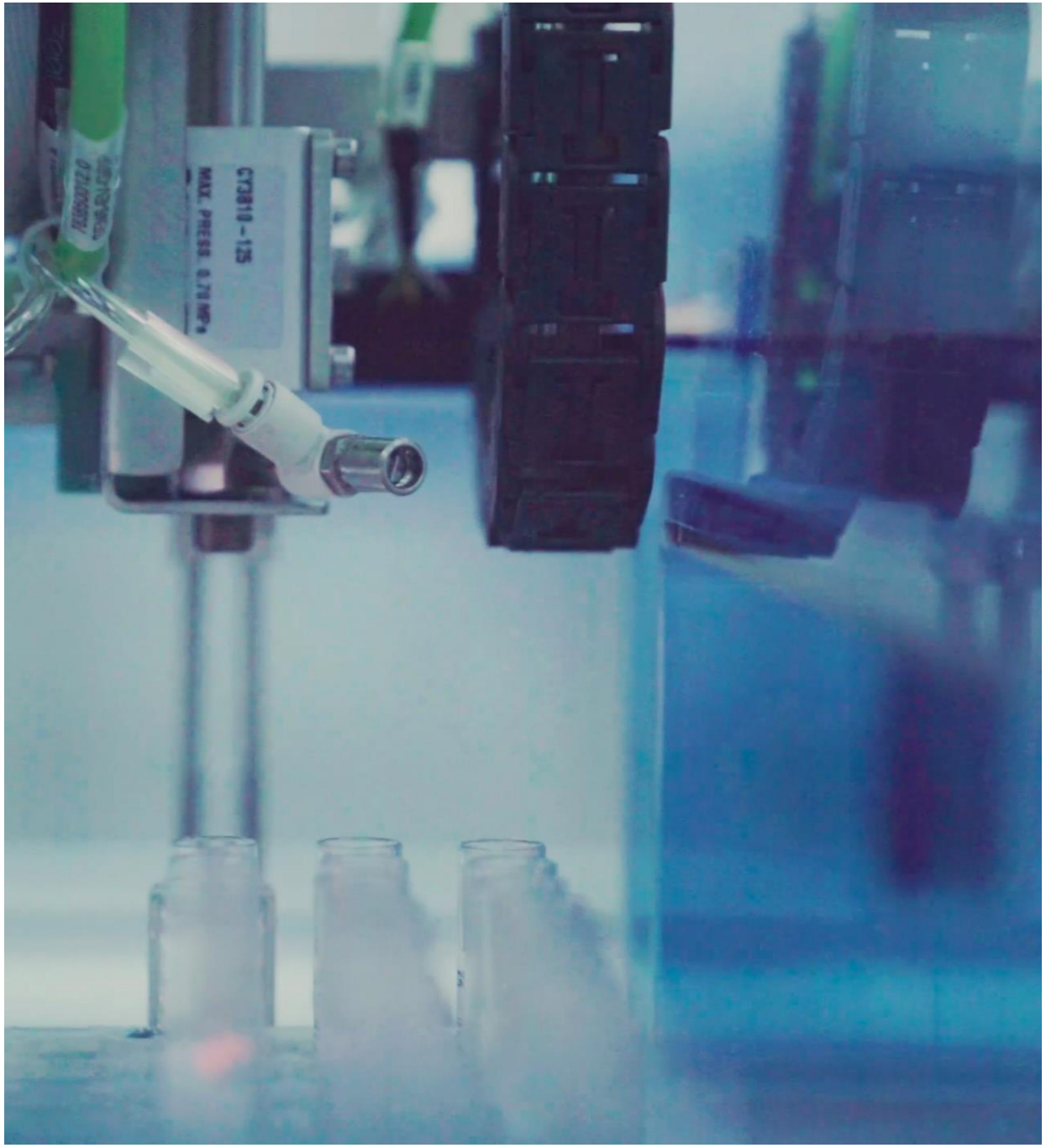
Dr. Makary's past writings and public statements indicate:

- Skepticism re: certain aspects of traditional medical establishment.
  - But also indicate support for reliance on valid scientific evidence.
    - May potentially lead to differing views from Secretary Kennedy in some areas.
- Criticism of the medical community and government response to the COVID-19 pandemic.
  - But advocated for accurate information and guidance about vaccinations, in contrast to Secretary Kennedy, who questioned utility of COVID-19 vaccines entirely.

ADDITIONAL RECENT LEADERSHIP CHANGES AT FDA

Top F.D.A. Vaccine Official Resigns, Citing Kennedy's 'Misinformation and Lies'

Dr. Peter Marks, a veteran of the agency, wrote that undermining confidence in vaccines is irresponsible and a danger to public health.



ANNOUNCED REGULATORY PRIORITIES AND ENFORCEMENT FOCUS

FDA:

- Streamline approval of biosimilars and generics
- Make America Healthy Again (MAHA)
  - Food additives
  - GRAS process/pathway
  - Infant formula
- Vaccines
- Obesity and chronic disease

DEPARTMENT OF JUSTICE:

- Remains to be seen whether reallocation of resources to:
  - immigration enforcement,
  - DEI, and
  - Illicit narcotics trafficking (including fentanyl)

  will negatively impact DOJ enforcement efforts in FDA-regulated space.
- Currently under consideration (per Reuters): major restructuring of Consumer Protection Branch
  - Moving defensive practice to the Federal Programs Branch
  - Moving criminal enforcement team to Criminal Division.

02

POTENTIAL IMPACT OF STAFFING LOSSES ON ENFORCEMENT AND PRODUCT REVIEWS

SIGNIFICANT STAFFING REDUCTIONS ACROSS DEPARTMENT OF HEALTH AND HUMAN SERVICES

Robert Califf • 2nd
Duke University
2h •

OK, i'm on a coast to coast flight, but i'm overwhelmed with messages about the firings. The FDA as we've known it is finished, with most of the leaders with institutional knowledge and a deep understanding of product development and safety no longer employed. I believe that history will see this a huge mistake. I will be glad if I'm proven wrong, but even then there is no good reason to treat people this way. It will be interesting to hear from the new leadership how they plan to put "Humpty Dumpty" back together again.

March 27, 2025
FDA, Food safety, Health, HHS, Nutrition

CIVIL EATS

RFK Jr. Cuts 3,500 Additional FDA Jobs in Sweeping Restructuring of HHS

Secretary of Health and Human Services Robert F. Kennedy Jr. announced a plan to make sweeping changes to his agency's structure and workforce this morning, with the most significant job cuts planned for the agency that regulates food safety, food additives, and antibiotic use in agriculture.

Of the 20,000 jobs Kennedy said he'll eliminate across the HHS, 3,500 will be at the Food and Drug Administration (FDA). He'll also cut 2,400 jobs at the Centers for Disease Control (CDC), which monitors infectious disease outbreaks, including the bird flu that is still spreading on poultry and dairy farms. The cuts are in addition to several thousand probationary employees fired from the HHS in February.

LEADERSHIP LOSSES AT FDA

Significant losses at highest levels:

- CDER: Dr. Patrizia Cavazzoni resigned in January 2025
- CDER: Peter Stein, Director of Office of New Drugs, resigned April 1, 2025.
- CBER: Director Peter Marks (eff. April 5, 2025) and Dep. Dir. Celia Witten (Feb. 2025)
- CDRH: Dr. Jeff Shuren, left the agency last year (June 2024)
- Jim Jones, FDA's deputy commissioner for foods, resigned in Feb. 2025
- CTP: Dr. Brian King removed April 1, 2025
- FDA Chief Medical Officer Hilary Marston

UNITS IMPACTED BY CUTS

- Deep cuts at FDA's Office of Prescription Drug Promotion, which regulates drug ads
- Deep cuts at FDA's Office of Manufacturing Quality, which protects the public from adulterated drugs and ensures compliance with good manufacturing practices
- Cuts to CBER's immuno-oncology staff
- Communications, public affairs, policy and FOIA staff

STAFF CUTS, RETURN TO OFFICE

- February 15: Probationary staff fired, with little explanation
  - Numbers unclear, reported to be >1,000 employees
  - At least 180 at CDRH (out of ~2,000), who are funded via user fees
  - Administration backtracked and re-hired many, including many in CDRH
- Significant additional cuts announced April 1
- Return to Office:
  - March 17th for employees within 50 miles
    - Parking, security lines, office space, confidentiality
  - April 28th for employees more than 50 miles away

IMPLICATIONS

- Review and approval deadlines under UFA programs
  - Anecdotal evidence for the moment
  - FDA dashboards and trackers are not updated real-time
  - Center for Tobacco Products delaying review of new applications
- Meeting attendance and timing
  - Providing early feedback on planned product applications
- "Minor" programs
  - FOIA, patent term extension
- ***Enforcement outsourcing?***
- ***Government affairs investments?***
- ***Trade associations at the forefront?***
- ***Recalibration of risk assessment?***

03

TRUMP EXECUTIVE ORDERS REGARDING DEREGULATION

EXECUTIVE ORDERS

- The Trump administration has issued a large number of Executive Orders (EOs) affecting large swaths of industries and agencies
  - Rescinded many Biden administration EOs, as well, including government-wide EO on AI
- Key EOs affecting FDA include:
  - EO 14151: Ending Radical and Wasteful Government DEI Programs and Preferencing (Jan. 20, 2025)
  - EO 14192: Unleashing Prosperity Through Deregulation (Jan. 31, 2025)
  - EO 14219: Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency" Deregulatory Initiative (Feb. 19, 2025)
    - Memorandum, Regulatory Freeze Pending Review (Jan. 20, 2025)
  - EO 14210: Implementing the President's "Department of Government Efficiency" Workforce Optimization Initiative (Feb. 11, 2025)
  - EO 14212: Establishing the President's Make America Healthy Again Commission (Feb. 13, 2025)
  - EO 14222: Implementing the President's "Department of Government Efficiency" Cost Efficiency Initiative (Feb. 26, 2025)

DEREGULATORY EXECUTIVE ORDERS

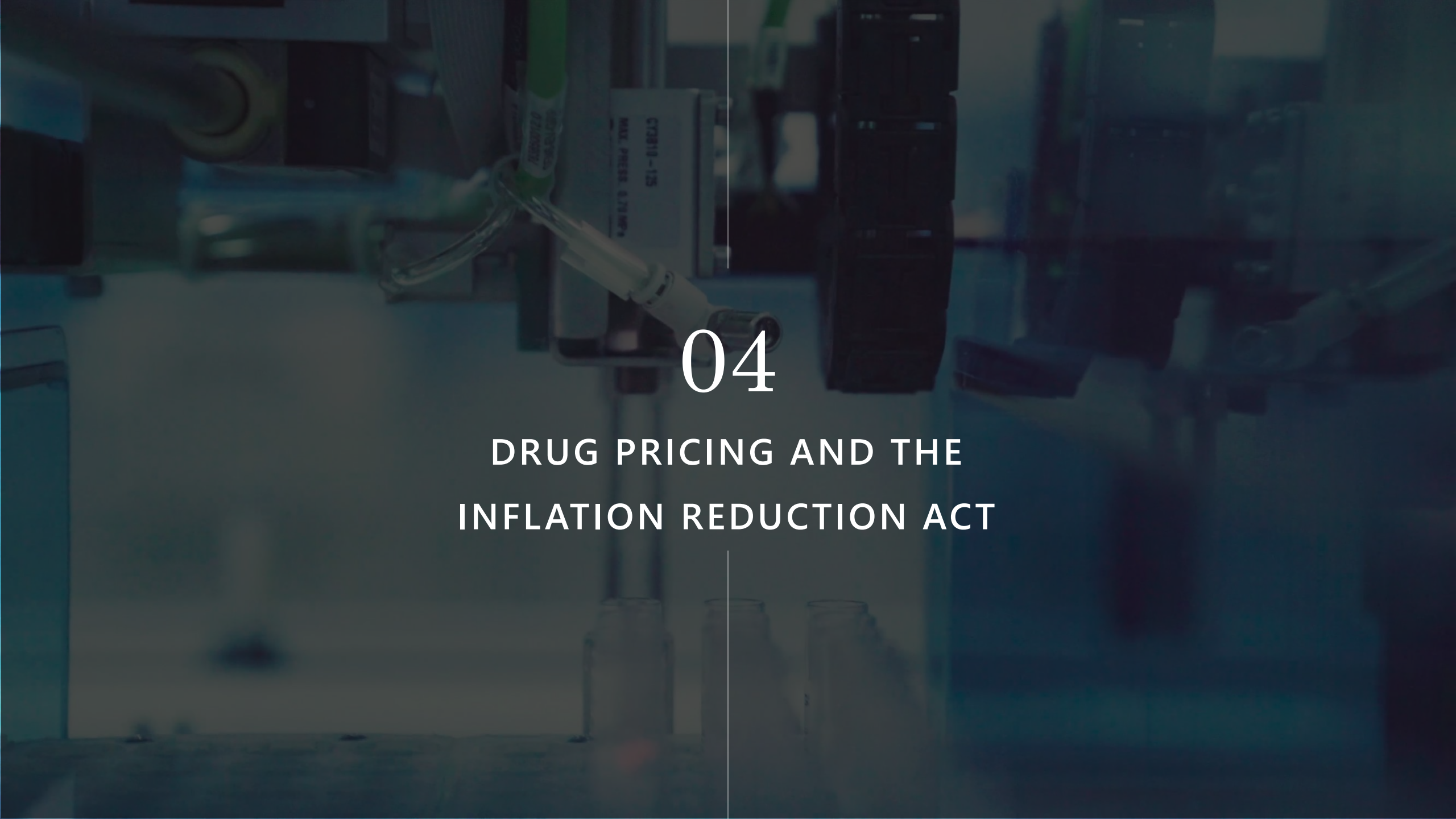
- **Memorandum, Regulatory Freeze Pending Review (Jan. 20, 2025)**
  - *No New Rules*: Agencies are prohibited from proposing or issuing any new rules until they have been thoroughly reviewed and approved by a President-appointed agency head.
  - *Withdrawal of Unpublished Rules*: Any rules that have been sent to the Office of the Federal Register (OFR) but not yet published must be withdrawn for review.
  - *Postponement of Effective Dates*: Agencies are instructed to consider postponing for 60 days the effective dates of any rules that have been published but have not yet taken effect to allow for review regarding questions of fact, law, and policy that the rules may raise. During the 60-day postponement, agencies may open a comment period for public input and reevaluate pending petitions.
- **EO 14192: Unleashing Prosperity Through Deregulation (Jan. 31, 2025)**
  - *10-for-1 rule*: 10 regulations to be identified for repeal, for each "regulation" promulgated
  - *Cost*: For FY2025, "total incremental cost of all new regulations, including repealed regulations" shall be less than zero, as determined by OMB

DEREGULATORY EXECUTIVE ORDERS

- **EO 14219: Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency" Deregulatory Initiative (Feb. 19, 2025)**
  - *Review Process*: Agencies have 60 days to identify classes of regulations that are purportedly
    - unconstitutional
    - unlawful delegations of legislative power
    - not best reading of statutory authority
    - implicate matters of social, political, or economic significance that are not authorized by clear statutory authority
    - impose significant costs upon private parties that are not outweighed by public benefits
  - *Enforcement Discretion*: de-prioritizing actions to enforce certain regulations
  - *Promulgation of New Regulations*: Agencies must submit all "regulations" for review by OIRA
    - "Regulation" shall have the meaning given to "regulatory action" in section 3(e) of Executive Order 12866, and also includes any "guidance document" as defined in Executive Order 13422 of January 18, 2007 (Further Amendment to Executive Order 12866 on Regulatory Planning and Review).

IMPLICATIONS OF DEREGULATORY EXECUTIVE ORDERS

- Uncertainty around key pending initiatives and rulemakings:
  - Food
    - FDA revoking the use of Red No. 3 in food and ingested drugs.
    - FDA proposed rule regarding Front-of-Package Nutrition Labeling.
    - FDA final rule on the “Healthy” nutrient content claim which is not effective until February 25, 2025.
    - FDA final rule on traceability (FSMA 204) which is not effective until January 2026.
    - USDA Food Safety and Inspection Service proposed rule regarding Salmonella as an adulterant at certain levels in raw poultry.
  - Drugs
    - FDA delayed until 27 May a rule on nonprescription drug products with an additional condition for non-prescription use (ACNU), which would establish certain product requirements, including application, labeling, and postmarket reporting requirements.
    - Firm-sponsored communications of scientific information regarding off-label use.
  - Laboratory Developed Tests
    - FDA final rule struck down in Texas district court; next steps uncertain?



04

DRUG PRICING AND THE INFLATION REDUCTION ACT

INFLATION REDUCTION ACT'S DRUG PRICE NEGOTIATION PROGRAM

- Part of Biden-era Inflation Reduction Act (IRA)
  - **January 17, 2025:** Centers for Medicare & Medicaid Services (CMS) announced its selection of the 15 Medicare Part D covered drugs subject to the second cycle of price negotiations (prices set to take effect on January 1, 2027): (1) Ozempic; Rybelsus; Wegovy; (2) Trelegy Ellipta; (3) Xtandi; (4) Pomalyst; (5) Ibrance; (6) Ofev; (7) Linzess; (8) Calquence; (9) Austedo; Austedo XR; (10) Breo Ellipta; (11) Tradjenta; (12) Xifaxan; (13) Vraylar; (14) Janumet; Janumet XR; and (15) Otezla
- Trump administration has continued to defend IRA drug price negotiation program against challenges from innovator pharma and biotech companies
- The Trump administration's CMS issued a press release on January 29, 2025, indicating potential changes to the process of negotiating prices for certain Medicare Part D drugs and seeking input from external stakeholders:

  "[a]s the second cycle begins under the Trump Administration, CMS is committed to incorporating lessons learned to date from the program and to considering opportunities to bring greater transparency in the Negotiation Program. CMS intends to provide opportunities for stakeholders to provide specific ideas to improve the Negotiation Program, consistent with the goals of achieving greater value for beneficiaries and taxpayers and continuing to foster innovation."

05

POTENTIAL IMPACT OF TARIFFS ON DRUG AND BIOTECH DEVELOPMENT

TARIFFS

- Increased tariffs mean that pharmaceutical and medical devices, which are generally not subject to customs duty, will now be subject to customs duty on import into the US (and into any other jurisdictions that impose retaliatory tariffs against US originating products). Customs duty is paid as a percentage of the customs value of the imported goods and is a cost that will be borne by the importer (depending on its contractual terms with its customer, it may be possible for this cost to be passed on to the latter).
- Impact of tariffs is difficult to predict, and implementation has been unpredictable
- Industry estimates range as high as $60B across pharma, life sciences and medical device industries
  - Could increase if sector-specific tariffs are imposed
  - China and Mexico play a large role in supply chain, particularly for medical devices
- Companies are scrambling to assess potential impacts on supply chain, sourcing and manufacturing costs
- BIO trade association reports that nearly 90% of US biotech companies rely on some imported materials for at least half of their FDA-approved products

INDUSTRY RESPONSE

- Pharma and biotech manufacturers have announced plans to “onshore” manufacturing
  - Eli Lilly said it will invest $27 billion in four new production facilities in the US
  - Johnson & Johnson announced plans to spend $55 billion in the US over the next four years, including three new manufacturing sites

06

AREAS OF POTENTIAL CONTINUITY

AREAS WHERE REGULATED INDUSTRY MAY EXPECT GREATER CONTINUITY

- China-Manufactured Products
  - Flavored Vaping Products (Electronic Nicotine Delivery Systems, or e-Cigarettes)
  - Chinese-manufactured dietary supplements
- Customs Violations
- Food Safety
- Rare Diseases and Oncology

Q&A

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